Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Sep 2026

Comparison of the effect of remifentanil and dexmedetomidine on surgeon satisfaction from surgical field and bleeding in rhinoplasty

Protocol summary

Study aim
Comparison of the effect of remifentanil and dexmedetomidine on surgeon satisfaction from surgical field and bleeding in rhinoplasty

Design
Double-blind randomized clinical trial

Settings and conduct
The drugs are prepared in the operating room by a nurse who is unaware of the type of study with label A in the dexmedetomidine group and label B in the remifentanil group and are given to a person who is unaware of the specialization of the groups for injection. The person assessing patients and patient satisfaction at the end of the study is also unaware of the allocation of study groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria:18-45 y/o, Patients undergoing rhinoplasty surgery Exclusion criteria: Patients with liver dysfunction, Renal dysfunction, Any known allergy or hypersensitivity to study drugs, analgesics abuse, opium addiction, Diabetes , Hemorrhagic disease, Using anticoagulants, Cerebrovascular disease, Heart block, Cardiovascular disease.

Intervention groups
In the Intervention group one patients will receive 1 µg / kg dexmedetomidine (PFIZER, USA) for 20 minutes and at the same time as induction begins with a dose of 0.6 µg / kg and continues until the end of the operation. In the Intervention group two simultaneously with the induction of anesthesia, in the remifentanil group (EXIR, IRAN), remifentanil infusion of 0.25 µg is started. It continued until the end of the operation.

Main outcome variables
Intraoperative bleeding, pain,surgeon satisfaction

General information

Reason for update
A more accurate record of the study method

Acronym

IRCT registration information
IRCT registration number: **IRCT20141009019470N112**
Registration date: **2021-04-01, 1400/01/12**
Registration timing: **prospective**

Last update: **2021-07-11, 1400/04/20**
Update count: **1**

Registration date
2021-04-01, 1400/01/12

Registrant information

Name
Farzaneh Masihi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 71 3647 4270

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masihif@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-23, 1400/02/03

Expected recruitment end date
2021-06-24, 1400/04/03

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of remifentanil and dexmedetomidine on surgeon satisfaction from surgical field and bleeding in rhinoplasty

Public title
Comparison of the effect of remifentanil and dexmedetomidine on surgeon satisfaction from surgical field and bleeding in rhinoplasty
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
18-45 years old Patients undergoing rhinoplasty surgery time of surgery is 7-10 days before menstruation time
Exclusion criteria:
Patients with liver dysfunction Renal dysfunction Any known allergy or hypersensitivity to study drugs Abuse of analgesics and any addiction to opioid, Diabetes mellitus Hemorrhagic disease Using anticoagulants Cerebrovascular disease Heart block Cardiovascular disease Morbid obesity Females whom experience nausea and vomiting in their menstrual cycle Revision rhinoplasty surgery
Age
From **18 years** old to **45 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method is based on permutation block randomization method with block size 6 by using the site www.sealedenvelope.com and Seed number: 266608829014794.
Blinding (investigator's opinion)
Single blinded
Blinding description
The drugs are prepared by a nurse who is unaware of the type of study with label A in the dexmedetomidine group and label B in the remifentanil group and are given to a person who is unaware of the specialization of the groups for injection. The person assessing patients and patient satisfaction at the end of the study is also unaware of the allocation of study groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street
City
Shiraz
Province
Fars
Postal code
7134844119
Approval date
2020-07-19, 1399/04/29
Ethics committee reference number
IR.SUMS.MED.REC.1399.241

Health conditions studied

1

Description of health condition studied
Rhinoplasty surgery
ICD-10 code
Z41.1
ICD-10 code description
Encounter for cosmetic surgery

Primary outcomes

1

Description
Amount of intraoperative bleeding
Timepoint
At the end of the surgery
Method of measurement
Observasion

2

Description
Post operative pain
Timepoint
At arrival to the recovery room and at, 45,30,15 minutes
Method of measurement
Visual analogue Scale

Secondary outcomes

1

Description
Patients’ satisfactions
Timepoint

After injection of intervention drugs in the recovery room and surgery ward

Method of measurement

Likert Scale

2

Description

Surgeon’ satisfactions

Timepoint

At the end of the surgery

Method of measurement

Likert Scale

Intervention groups

1

Description

Intervention group: In the Intervention group one patients will receive 1 µg / kg dexmedetomidine (PFIZER, USA) for 20 minutes and at the same time as induction begins with a dose of 0.6 µg / kg and continues until the end of the operation..

Category

Prevention

2

Description

Intervention group: In the Intervention group two:Simultaneously with the induction of anesthesia, in the remifentanil group (EXIR, IRAN), remifentanil infusion of 0.25 µg is started. It continued until the end of the operation.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Khalili Hospital

Full name of responsible person

Maryam Nemati

Street address

Khalili Educational Hospital, Khalili Street -

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Shiraz

Province

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1433671348

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khalili.hospital@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Abbas Rezaianzadeh

Street address

Vice chancellor of research,7th floor of central building of Shiraz University of Medical Sciences, Zand street

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Maryam Nemati

Position

Anesthesiology resident/physician

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Reza Jouybar
Position
Cardio-anesthesiologist
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Farzaneh Masihi
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MS in English Teaching, BS in anesthesia/English Consultant
Latest degree
Master
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
It is against the policies of the center.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available